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Elizabeth Arwine, Esq.
USAMRMC
504 Scott Street
Fort Detrick, MD 21702

EXAMINER	
KANTAMNENI, SHOBHA	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,446	JIANG ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-6, 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment received on 04/12/2007, wherein claims 1-2, and 27 have been amended, and claims 7-11 have been cancelled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claims 1-6, 27-31 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The recitation, "febrifugine/halofuginone/isofebrifugine derivative compound having lower toxicity to mammalian neuronal and macrophage cells" in this claim renders the claim herein indefinite. The recitation "having lower toxicity" in claim 1 is a relative term which renders the claim indefinite. The term "having lower toxicity" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

2) The recitation, derivatives of febrifugine/halofuginone/isofebrifugine are not clearly defined in the specification. Hence, one of ordinary skill in the art could not

ascertain and interpret the metes and bounds of the patent protection desired as to "febrifugine/halofuginone/isofebrifugine derivative" herein, since one of ordinary skill in the art would clearly recognize that many widely varying groups could possibly substitute the compounds herein would read on the "derivative" of "febrifugine/halofuginone/isofebrifugine". Given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the derivative' of "febrifugine/halofuginone/isofebrifugine" herein encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Takaya et al. (J. Med. Chem. 1999, 42, pages 3163-3166, PTO-892).

Takaya et al. disclose a method of treating protozoan infection by administering an effective amount of quinazolinone compounds such as febrifugine, isofebrifugine, and derivatives thereof such as Df-1(3), Df-2(4). The compounds therein are effective against *P.falciparum*, and *P.berghei*. It is also disclosed that Df-1, compound 3, was

found to be equally effective against *P.berghei in vivo* as the clinically used drug chloroquine. The compounds therein are administered intraperitoneally. See abstract; page 3164, right hand column, Table 2.

The recitation "compound having lower toxicity to mammalian neuronal and macrophage cells" is the property of febrifugine/isofebrifugine compound and derivatives thereof such as Df-1(3), Df-2(4), and thus is inherently present in febrifugine/isofebrifugine compound and derivatives thereof such as Df-1(3), Df-2(4).

Thus, Takaya et al. anticipates instant claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al. (Trends in Heterocyclic Chemistry, Vol.7, 2001, pages 65-74, PTO-892).

Takeuchi et al. discloses a method of treating protozoan infections by administering effective amounts of febrifugine, or isofebrifugine compound. Note isofebrifugine is a derivative of febrifugine. Febrifugine derivatives include quinazolinone compound as instantly claimed in claim 27. See abstract; Figure 1, page 65; page 72, Figure 4. It is also disclosed that febrifugine (+), and isofebrifugine possess antimalarial activity, and are useful in the treatment of protozoan infections which include protozoa

such as *P.falciparum*, and *P.berghei*. See page 73, Table III. In vivo, and in vitro data is also disclosed.

The recitation "compound having lower toxicity to mammalian neuronal and macrophage cells" is the property of febrifugine/isofebrifugine compound, and thus is inherently present in febrifugine/isofebrifugine compound.

Thus, Takeuchi et al. anticipates instant claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (EP 1 076 057, PTO-892).

Kobayashi et al. discloses a method of treating protozoan infections by administering effective amounts of febrifugine, or isofebrufugine. Note isofebrifugine is a derivative of febrifugine. See abstract. It is also disclosed that febrifugine (+) possess antimalarial activity, and is useful in the treatment of protozoan infections which include protozoa such as *P.falciparum*. See page 8, paragraph [0049]-page 10, paragraph [0061].

The recitation "compound having lower toxicity to mammalian neuronal and macrophage cells" is the property of febrifugine/isofebrifugine compound, and thus is inherently present in febrifugine/isofebrifugine compound.

Thus, Kobayashi et al. anticipate instant claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaya et al. (J. Med. Chem. 1999, 42, pages 3163-3166, PTO-892) as applied to claim 1 above, and further in view of Takeuchi et al. (Trends in Heterocyclic Chemistry, Vol.7, 2001, pages 65-74, PTO-892).

Takaya et al. is as discussed above.

Takaya et al. does not explicitly teach the employment of particular quinazolinone compound as in claim 27, in the method of treating protozoan infections.

Takeuchi et al. discloses a method of treating protozoan infections by administering effective amounts of febrifugine, or isofebrufugine. It is further taught that febrifugine derivatives are also screened for antimalarial activity, and febrifugine

derivatives therein include compound as in claim 27. See abstract; Figure 1, page 65; page 72, Figure 4, 16f.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the particular quinazolinone compound as in claim 27 for treating protozoan infections, wherein protozoa is *plasmodium falciparum* or *plasmodium berghei.*

One of ordinary skill in the art at the time of invention would have been motivated to administer quinazolinone compound as in claim 27, with reasonable expectation of treating protozoan infections because febrifugine is known to be useful in the treatment of protozoan infections, wherein protozoa is *plasmodium falciparum* or *plasmodium berghei*, and according to Takeuchi et al. the particular quinazolinone compound as in claim 27 is a derivative of febrifugine. Thus, one of ordinary skill in the art at the time of invention would reasonably expect that the derivatives of febrifugine would have similar properties and therapeutic effects as febrifugine. Note that Takeuchi et al. teaches that febrifugine derivatives were screened for antimalarial activity.

Therefore, one of ordinary skill in the art would have been reasonably expected that the instant particular quinazolinone derivaitve, would have same or substantially similar beneficial therapeutic effects and usefulness as febrifugine in methods for treating protozoan infections, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g, Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and if the claimed invention and the structurally similar prior art species share any useful

property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

Response to Applicant's Arguments:

Applicant's arguments have been considered, but not found persuasive. Takaya et al. disclose a method of treating protozoan infection by administering an effective amount of quinazolinone compounds such as febrifugine, isofebrifugine, and derivatives thereof such as Df-1(3), Df-2(4). Takeuchi et al. teach that febrifugine derivatives, such as a compound as in claim 27 is screened for antimalarial activity. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ febrifugine derivatives, compound as in claim 27 with reasonable expectation of success of treating protozoan infection because 1) both Takaya et al, and Takeuchi et al. teach that febrifugine derivatives possess antimalarial activity, and 2) febrifugine derivative, a compound as in claim 27 was screened by Takeuchi et al. as a potential antimalarial compound.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER